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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,913	07/14/2003	Edward Faeldt	9000/2022	7967

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EXAMINER	
ZHOU, SHUBO	

ART UNIT	PAPER NUMBER
1631	

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06/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,913	FAELDT ET AL.	
	Examiner	Art Unit	
	SHUBO (Joe) ZHOU	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30 and 32-37* is/are pending in the application.

4a) Of the above claim(s) *7-8, 13-14, 18-20, 27-28, and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendments

Applicant's amendment to the claims field 3/20/09 is acknowledged and entered.

Status of Claims

Claim 31 has been canceled.

Claims 1-30 and 32-37 are pending.

Claims 7-8, 13-14, 18-20, 27-28, and 36 have been previously withdrawn from further consideration.

Claims 1-6, 9-12, 15-17, 21-26, 29-30, 32-35, and 37 are presently under examination.

Claim Rejections-35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9-12, 15-17, 21-26, 29-30, 32-35, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Some of the rejections below under the second paragraph are reiterated from the previous Office action mailed on 3/24/08, and some are newly added, which is

necessitated by applicant's amendment filed 3/20/09. Those set forth in the previous Office action but not reiterated herein are withdrawn in view of applicant's amendment.

Claim 1 recites the limitation "providing a population of transgenic insects comprising a human neurodegenerative disease gene." The metes and bounds of the limitation are not clear because it is unclear whether each member of the population comprises the human neurodegenerative disease gene or the population as while comprises the human neurodegenerative disease gene, i.e. some members may not comprise the human gene. As such, claims 1-6, 9-12, 15-17, 21-26, 29-30, 32-35, and 37 are indefinite.

Claim 2 and its dependent claims are rejected for containing the same limitation.

Response to Argument. This rejection is reiterated from the previous Office action. Applicant's argument filed 3/20/09 is on the ground that the amendment filed 3/20/09 overcomes the rejection. See page 10 of the response. This is unpersuasive because the metes and bounds of the amended claims are still unclear. The amended claims, e.g. claim 1, now recite "providing a population of transgenic insects, said transgenic insects of said population comprising a human neurodegenerative disease gene." It is still unclear whether all or only some individuals of the population comprise the human neurodegenerative disease gene. One skilled in the art would understand that if only certain, but not all, members of the insect population comprise the human gene, one could say that the insects of the population comprise the gene. If it is intended that each and every member of the population comprises the human gene, it should be clearly so indicated.

The amended claim 1 recites "identifying a difference between said trait before administration of said test agent and after administration of said at least one test agent ...." It is confusing in that it's unclear whether a difference is intended for "said test agent" and "said at lest one test agent." This rejection is necessitated by applicant's amendment filed 3/20/09.

Clarification of the metes and bounds of the claims is requested.

Claim Rejections-35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351 (a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 9-12, 15-17, 21-26, 29-30, 32-35, and 37 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Botas, US 2004/0177388 in view of Roberts et al. (Journal of Leukocyte Biology, Vol. 68, pages 627-632, Nov. 2000).

This rejection is necessitated by applicant's amendment.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The claims are drawn to a method for determining whether a test agent has an effect on a population of insects, the method comprising providing a population of transgenic insects comprising a human neurodegenerative disease gene; identifying a trait of a specimen in the population before the administration of the test agent; administering the test agent to the population; creating a plurality of digital image frames of a movie

showing a trait of specimens in the population; and identifying a difference between the trait before administration of the test agent and after administration of the test agent, wherein a difference identifies the test agent as having an effect on the population of insects.

Botas discloses a method for screening for a compound having activity against neurodegenerative disorder in transgenic insects *(e.g.,* Drosophila) comprising providing a population of transgenic insects having a human neurodegenerative disease gene (claims 48-57), administering an agent, creating a plurality of frames of images showing a trait in a population using Bio-Rad MRC-1024 confocal imaging system ([0299]-[[0303] and Figs 1A through 1G, 2A through 2G, 6A through 6K, and especially 7A through 7A), and correlating the trait with the effect ([0288]-[292]). Botas discloses quantifying a trait ([0300]), as in the instant claims 3-4. Botas discloses modifying and quantifying a climbing behavior [0300]-[0301], as in instant claims 5-6. Botas discloses an agent screening assay using various compounds and a test and reference fly populations and ranking agents according to their activity (claims 48-52 therein and [0300]-[0318]), as in instant claim 9. Botas discloses determining an agent and reference phenoprofile (i. e., a trait and a quantitative characteristic of the trait), comparing both phenoprofiles, and selecting and agent (claims 48-52, [0300]-[0301]), as in instant claims 10-12, 15-17, and 21-23. Botas discloses an insect phenotype with characteristics of a mammalian disease (claim 56 therein), as in instant claims 24-26, 29-30, 33, 35, and 37. Botas discloses transgenes for gene encoding a polypeptide with an expanded polyglutamine tract [0007], as in instant claim 32. Botas discloses mutation which results in loss or gain of a function ([0007]-[0011]; claims 48-58 therein], as in instant claim 34.

Botas does not expressly use the term "movie."

However, Botas discloses that an image series of 40 focal planes are taken from one sample. See at least paragraph [0342]. The instant specification states that the term "movie" has its normal meaning in the art and refers a series of images (e.g., digital images) called "frames" captured over a period of time. See page 27. It would be readily apparent to one skilled in the art at the time of the invention that the series of 40 images by Botas were done over time, and thus would be considered as a movie.

Or alternatively, making a movie instead of still images would have been obvious to a person of ordinary skill in the art at the time the invention was made over Botas in view of Roberts et al.

Roberts et al. disclose creating a movie and performing time-lapse recordings of cells overnight to observe changes in endosome structure and activity after activation of a GFP labeled protein. They also disclose that the time-lapse recordings were made with Bio-Rad MRC 1024 confocal microscopy, which is the same instrument used by Botas. See at least Fig. 1 and page 628, right column. One having ordinary skill in the art would have been motivated to modify Botas to take time lapse images and make a movie as it would have been well known in the art that a movie having multiple images over time could reveal things that a still image might not and could observe changes of fluorescense, as used by Botas, over time. There would have been a reasonable expectation of success as Roberts et al. disclosed the details of doing so.

Double Patenting

Claims 1-6, 9-12, 15-17, 21-24, 25-26, 32-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9-12, 15-17, 21-24, 25-26, 29, 30-33 of copending Application 10/676,424 ("App.'424"). A group of claims (29 and 30) is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 29 of App. '424.

Claim 30 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 29 of copending Application 10/676,424 ("App. '424"), in view of Botas, US 2004/0177388.

These rejections are reiterated from the previous Office actions.

In the response filed 3/20/09, applicant did not dispute the rejections but stating that applicant will consider filing a terminal disclaimer upon notification of otherwise allowable claims.

Applicant is advised that until a terminal disclaimer if filed or claims of the copending and/or the instant application are amended so that the claimed subject matter of the copending and the instant applications is patentably distinct, the rejection under the judicially created doctrine of double patenting will be maintained and no allowable subject matter will be indicated. A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Claim Objections

Claim 2 and its dependent claims are objected to because of the following reasons including informalities:

Claim 2 does not end with a punctuation mark.

Appropriate correction is required.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor,

Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER